UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/051,843	06/29/1998	TRACY WILLSON	11373	8485

7590 07/25/2006

SCULLY SCOTT MURPHY & PRESSER
400 GARDEN CITY PLAZA
GARDEN CITY, NY 11530

EXAMINER	
HOWARD, ZACHARY C	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 07/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/051,843	WILLSON ET AL.	
	Examiner	Art Unit	
	Zachary C. Howard	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,7-10,25,28-30 and 36-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,7-10,25,28-30 and 36-52* is/are rejected.

7)☒ Claim(s) *37,39,40 and 43* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 May 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on 5/10/06 has been entered.

Status of Application, Amendments and/or Claims

The amendment of 5/10/06 has been entered in full. Claims 30, 36, 37, 42-45 and 48-51 are amended. Claims 11-24, 26, 27 and 31-35 are canceled. Claims 3-6 were previously cancelled by Applicants.

Claims 1, 2, 7-10, 25, 28-30 and 36-52 are under consideration in the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Note regarding Claim 37

The Examiner notes that two different versions of claim 37 were presented by Applicants in the 1/11/2002 response. On page 6, version #1 of claim 37 recites "An isolated nucleic acid molecule comprising SEQ ID NO: 3". However, on page 18, version #2 of claim 37 recites "An isolated nucleic acid molecule comprising a nucleic acid sequence as set forth in SEQ ID NO: 3". In the previous Office Action, the Examiner did not notice this discrepancy and referred only to version #2 of the claim (e.g., see page 16 of the 11/7/2005 Office Action). In the 5/10/06 response, Applicants have amended claim 37; however, version #1 has been used as the basis for amending the claim. To facilitate prosecution, the Examiner will consider version #1 as the true version of claim 37, and will examine claim 37 as it is currently presented by Applicants.

Specification

The disclosure is objected to because of the following informalities:

(1) All of the parts of Figure 1 are not identified clearly in the Brief Description of the Figures. Applicants have amended the specification 5/10/2006 such that the Brief Description of the Figure 1 refers to Figures 1A to 1G; however, the Drawings submitted 4/22/1998 contain seven figures relating to Figure 1, labeled as follows: Fig. 1; Fig. 1(i); Fig. 1(ii); Fig. 1(iii); Fig. 1(iv); Fig. 1(v); and Fig. 1(vi). If Applicants wish to refer to these Figures as Figure 1A to 1G in the specification, it is suggested that replacement drawings be submitted that are labeled Figure 1A through 1G.

Appropriate correction is required.

Priority

Acknowledgement is made of Applicants' claim for foreign priority under 35 U.S.C. 119(a)-(d) based on applications file din Australia on 10/23/95, 12/22/95, and 9/9/96 numbered PN-6135, PN-7276, and PO-2208. The Examiner notes that a certified copy of each of these applications was submitted by Applicants 3/24/20003.

It is noted that the priority applications do not teach the entirety of instant SEQ ID NO: 3 or 4. Application PN-6135, filed 10/23/1995, does not teach SEQ ID NO: 3 or 4, or any human IL-13 receptor sequences. Application PN-7276, filed 12/22/1995 and application PO-2208, 9/9/1996, each teach partial human IL-13 receptor sequences; specifically each application teaches a SEQ ID NO: 3 that consists of 1248 nucleic acid residues, and a SEQ ID NO: 4 that consists 401 amino acids. These sequences consist of partial sequences of instant SEQ ID NO: 3 (1383 nucleic acids) and SEQ ID NO: 4 (426 amino acids). Therefore, with regard to the full-length sequences, the earliest priority date to which the instant application merits priority is the filing date of the instant application (10/23/1996).

Withdrawn Objections and/or Rejections

The following page numbers refer to the previous Office Action (11/7/2005).

The rejection of claims 45 and 46 under 35 U.S.C. § 101 at pg 6 because the claimed invention is directed to non-statutory subject matter is *withdrawn* in view of Applicant's amendments to the claims.

The rejection of claims 30, 36, 45 and 46 under 35 U.S.C. § 112, 1st paragraph is *withdrawn in part*. Specifically, the rejection of these claims for encompassing non-isolated host cells (as set forth at pg 10-12) is withdrawn in view of Applicants' amendments to the claims. As such, claims 45 and 46 are no longer rejected under 35 U.S.C. § 112, 1st paragraph. It is noted that claims 1, 2, 7-10, 25, 28-30, 36-44, and 47-52 remain rejected under 35 U.S.C. § 112, 1st paragraph (see below).

The rejection of claims 38-40 under 35 U.S.C. § 102(b) as anticipated by Larsen (1990) is *withdrawn* in view of Applicants' amendments to the claims.

Please see new claim objections and rejections, below.

Claim Objections

Claims 37, 39, 40 and 43 are objected to because of the following informalities:

(1) Claim 37 recites, "the nucleotide sequence as set forth SEQ ID NO: 3". This phrase appears to be missing the word "in"; therefore the claim should be corrected to recite, "the nucleotide sequence as set forth in SEQ ID NO: 3", or simply "the nucleotide sequence of SEQ ID NO: 3".

(2) The word "extracellular" is spelled inconsistently in the claims. Claim 38 spells the word "extracellular" (which is the standard usage in the art). Claims 39 and 40 each depend from claim 38 and use, respectively, the phrases "said extra - cellular" and "said extra cellular". Claims 39 and 40 should be corrected to be consistent with claim 38.

(3) In claim 43, the first letter of the word "claim" is capitalized (i.e., "of Claim 37"). This letter should be in lowercase as in the other claims (i.e., "of claim 37").

Appropriate correction is required.

Claim Rejections - 35 USC § 112, 1st paragraph

Claims 1, 2, 7-10, 25, 28-30, 36-44 and 47-52 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid molecule encoding a polypeptide comprising the entire extracellular domain of SEQ ID NO: 4, does not reasonably provide enablement for an isolated nucleic acid encoding a derivative of SEQ ID NO: 4 that does not comprise the entire extracellular domain of SEQ ID NO: 4. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Applicants' arguments (5/10/06; pg 13-15) as they pertain to the rejection have been fully considered but are not deemed to be persuasive for the following reasons.

In the response dated 5/10/06, Applicants submit the specification provides sufficient guidance for one skilled in the art to isolate and use nucleic acids encoding derivatives of a receptor of SEQ ID NO: 4. Applicants submit that the specification defines the term "derivative" as including mutants, parts, fragments, portions, homologues and analogues, including functional or non-functional derivatives. Applicants submit that the specification describes the cloning of human IL-13Rα (Example 11) and shows an amino acid sequence alignment of murine IL-13Rα and its human homolog at the amino acid level (Figure 7). Applicants argue that one skilled in the art can use the alignment to identify domains in human IL-13Rα, such as the extracellular domain (which corresponds to residues Thr28-Thr346 in SEQ ID NO: 4) or Ig domain (Thr28-Ser118). In support, Applicants submit WO 00/18932 as teaching cytokine traps utilizing the extracellular domain of the present application.

Applicants' arguments have been fully considered but are not found persuasive. The Examiner has fully considered WO 00/18932; however, as noted in the previous action, the specification provides enablement for polynucleotides encoding polypeptides comprising the entire extracellular domain of SEQ ID NO: 4. Such polypeptides can be used to bind IL-13, as shown in the specification for the soluble murine IL-13Rα. However, the claims are not limited to polypeptides comprising the entire extracellular

domain of SEQ ID NO: 4 (residues 28-346). Instead, the claims encompass variant polypeptides wherein one or more amino acid residues are altered within residues 28-346 of SEQ ID NO: 4. It would require undue experimentation to make and test the extremely large genus of variants encompassed by the claims. Residues 28-346 consist of 318 amino acids; each of which can independently changed to one of twenty other amino acids; furthermore, the claims encompass any number of insertions or deletions within these 318 amino acids.

It is noted that the claims that recite nucleic acids comprising "a nucleotide sequence as set forth in SEQ ID NO: 3" have been broadly interpreted to encompass any shorter nucleotide sequences that are found within the longer sequence of SEQ ID NO: 3. Similarly, claims that recite nucleic acids comprising a sequence encoding "an amino acid sequence as set forth in SEQ ID NO: 4" have been broadly interpreted to encompass any nucleic acid comprising any shorter nucleotide sequence that encodes a fragment of SEQ ID NO: 4.

Applicants agree that the claims encompass "mutants, parts, fragments, portions, homologues and analogues, including functional or non-functional derivatives." However, the specification does not enable one of skill in the art to make and use nucleic acids encoding non-functional derivatives of SEQ ID NO: 4. The ability to produce antibodies to non-functional derivatives of SEQ ID NO: 4 does not provide a use for such non-functional derivatives. Antibodies to a protein are only useful if the protein itself has a use.

As set forth previously, Applicants have provided little or no guidance beyond the mere presentation of sequence data to enable one of ordinary skill in the art to determine, without undue experimentation, the positions in the protein which are tolerant to change (e.g. such as by amino acid substitutions or deletions), and the nature and extent of changes that can be made in these positions. The references of Wells (1990) and Ngo (1995) were cited in the previous Office Action in support of the argument that certain positions in a protein can tolerate only relatively conservative substitutions or none at all. The references of Bork (2000); Skolnick and Fetrow (2000); Doerks *et al.* (June 1998); Smith and Zhang (November 1997); Brenner (April 1999);

and Bork and Bairoch (October 1996) were cited in the previous Office Action in support of the argument that function cannot be predicted by structure alone. The specification teaches preparation of soluble murine IL-13Rα; the ability of murine IL-13Rα to bind IL-13 (Example 12); and describes several sub-domains of murine IL-13Rα including a signal sequence, transmembrane domain, extracellular domain (Thr37-Thr344), Ig-like domain (27-117) and haemopoietin receptor domain (118-340) (Examples 6 and 12); and provides an alignment of murine and human IL-13Rα, such that one skilled in the art could determine the location of similar sub-domains in human IL-13Rα. However, the specification does not provide any further guidance as to which variants of murine IL-13RAα retain binding to IL-13. The Examiner agrees that variants that comprise the entire unaltered extracellular domain of human IL-13Rα would probably retain binding to IL-13. However, the claims include a wide range of variants including those with multiple mutations within the extracellular binding domain. The claims also include smaller fragments of the extracellular binding domain, such as the aforementioned domains, none of which have been shown to bind IL-13 when prepared in isolation from the rest of the protein. While some of the claims include the limitation that the polypeptide variants exhibit characteristics (ability to bind IL-13) of the parent polypeptide of SEQ ID NO: 4, the claims encompass an enormous scope of variants of SEQ ID NO: 4 in which any number of changes can be made to the sequence. Applicants do not disclose any actual or prophetic examples on expected performance parameters of any of the possible variants of polypeptides of SEQ ID NO: 4, other than a sole soluble receptor consisting of the entire extracellular domain of the protein. The specification has not provided a working example of the use of any other variants of the polypeptide of SEQ ID NO: 4, nor sufficient guidance so as to enable one of skill in the art to make such a variant. The specification has failed to teach which amino acids of SEQ ID NO: 4 could be modified so as to produce a polypeptide that is not identical to SEQ ID NO: 4 and yet still retain the activity of the polypeptide of SEQ ID NO: 4. The specification merely invites the skilled artisan to screen an extremely large genus of variants to determine whether or not each variant has the ability to bind IL-13.

Due to the large quantity of experimentation necessary to generate the large number of derivatives recited in the claims and possibly screen same for activity, the lack of direction/guidance presented in the specification regarding which structural features are required in order to provide activity, the absence of working examples directed to same, the complex nature of the invention, the state of the prior art which establishes the unpredictability of the effects of mutation on protein structure and function, and the breadth of the claims which fail to recite any structural or functional limitations, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Claim Rejections - 35 USC § 112, 1st paragraph, written description

Claims 1, 2, 7-10, 25, 28-30, 36-44 and 47-52 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In the response dated 5/10/06, Applicants submit the specification describes (at least implicitly) various variants and fragments of SEQ ID NO: 4 in sufficient detail for one skilled in the art. Applicants submit that the specification defines the term "derivative" as including mutants, parts, fragments, portions, homologues and analogues, including functional or non-functional derivatives. Applicants submit that the specification describes the cloning of human IL-13Rα (Example 11) and shows an amino acid sequence alignment of murine IL-13Rα and its human homolog at the amino acid level (Figure 7).

Applicants' arguments have been fully considered but are not found persuasive. The claims encompass a genus of isolated nucleic acids encoding derivatives of a haemopoietin receptor (HR) of SEQ ID NO: 4, host cells comprising said nucleic acids, and methods of producing recombinant polypeptides. A description of a genus of polynucleotides encoding a genus of polypeptides may be achieved by means of a

recitation of a representative number of polypeptides, defined by amino acid sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The instant specification discloses isolated cDNAs having the sequence of SEQ ID NO: 1 and 3, which encode polypeptides having the sequence SEQ ID NO: 2 and 4. The specification further describes the soluble extracellular domain of the polypeptide of the murine IL-13Rα, and provides an alignment of murine IL-13Rα with human IL-13Rα, such that the specification provides sufficient description of the extracellular domain (residues 28-346). A polynucleotide encoding a polypeptide comprising said extracellular domain could be used to produce a polypeptide that binds IL-13. However, the claims are not limited to polypeptides that comprise the extracellular domain of SEQ ID NO: 4 (residues 28-346). Instead, the claims encompass polynucleotides that vary substantially in length and also in nucleotide composition. The broadly claimed genus additionally encompasses polynucleotides that may be completely unrelated to the polynucleotide SEQ ID NOs: 1 and 3. For example, in claim 2, a "derivative" of SEQ ID NO: 1 or 3 that encodes a receptor capable of interaction with a derivative of IL-13 does not actually have any particular identity with SEQ ID NO: 1 or 3. The instant disclosure of SEQ ID NOs: 1 and 3, and the extracellular domain of each, does not adequately describe the scope of the claimed genus, which encompasses a substantial variety of subgenera including full-length proteins, chimeric proteins, fusion proteins, allelic variants, and derivatives. The derivatives or variants may have no known or disclosed function. For example, in claim 2, a derivative of SEQ ID NOs: 1 or 3 that is capable of interaction with a derivative of IL-13 may be a protein completely unrelated to instant invention, structurally and functionally. The polypeptides, encoded by polynucleotides isolated by hybridization may be completely unrelated to the polypeptide of SEQ ID NOs: 2 or 4. Further, polypeptides, comprising fragments, may also be completely unrelated to the polypeptide of SEQ ID NOs: 2 or 4. As such, the instant specification fails to provide sufficient descriptive information, such as definitive structural or functional features of

the claimed genus of polypeptides. The alignment between the murine and human IL-13Rα does not provide sufficient descriptive information to identify those derivatives of the receptor that retain the functionality of the parent polypeptide.

Claim Rejections - 35 USC § 112, 1st paragraph, new matter

Claims 38-44 and 48-51 are also rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement because the claims contain new matter.

Each claim encompasses a genus of nucleic acids that does not have support in the specification as originally filed.

Claims 38-42 each encompass a genus of isolated nucleic acids comprising an extracellular domain of an IL-13 haemopoietin receptor. Claim 38 encompasses a genus of isolated nucleic acids "comprising a sequence of nucleotides that encodes an extracellular domain of a IL-13 haemopoietin receptor." The term "IL-13 haemopoietin receptor" is not defined in the specification; therefore, the term has been interpreted broadly to encompass any IL-13 receptor. The language used, i.e., "a sequence of nucleotides that encodes an extracellular domain" indicates that the genus is not limited to any particular portion of an extracellular domain (ECD). Claims 39 and 40 each depend from claim 38 and limit the ECD to either an immunoglobulin-like domain (ID; claim 39) or an haemopoietin receptor domain (HRD; claim 40). Again, claims 39 and 40 broadly encompass any IL-13 receptor. Claim 41 depends from claim 39 and limits the ID to consisting essentially of amino acids 28-118 of SEQ ID NO: 4. Claim 42 depends from claim 40 and limits the HRD to consisting essentially of amino acids 119-341 of SEQ ID NO: 4.

The specification teaches the following regarding isolated nucleic acids encoding extracellular domains of hematopoietin receptors. The specification refers to soluble NR4 (IL-13Rα) on pages 7, 9, and 27. On page 27 the specification discusses uses of soluble IL-13Rα, e.g. to prevent interaction between IL-13 and NR4 (which is membrane bound). Page 37 discloses the characterization of the murine NR4, and teaches that the

extracellular region of the protein of SEQ ID NO: 2 contain an immunoglobulin domain (amino acids 27-117), in addition to a typical haemopoietin receptor domain (amino acids 118-340). Page 40 teaches production of soluble murine IL-13Rα by using PCR primers specific for the DNA encoding the extracellular region from Thr27 to Thr344. The specification further provides an alignment between murine IL-13Rα and human IL-13Rα, showing strong homology between the extracellular domain of the murine sequence (residues Thr27 to Thr344) and human sequence (residues Thr28 to Thre346, corresponding to residues 28-346 in SEQ ID NO: 4).

As stated above, claim 38 encompasses any extracellular domain from any IL-13 hematopoietin receptor. In addition to nucleic acids encoding full-length receptors, this genus encompasses nucleic acids comprising fragments consisting solely of extracellular domains. The specification teaches a single example of this, a nucleic acid consisting of the extracellular domain of SEQ ID NO: 2. Due to the strong homology between SEQ ID NO: 2 and 4, and the general teachings of the specification about soluble IL-13Rα, a nucleic acid consisting of the extracellular domain (Thr27 to Thr344) of SEQ ID NO: 4 would also flow naturally from the specification. However, there is no conception in the specification of a genus of isolated nucleic acid molecules comprising any extracellular domain from any IL-13 hematopoietin receptor (HR). Nor does this genus flow naturally from the disclosure of the specification. Therefore, the specification as originally filed lacks support for claims 38-42.

Claim 43, 44 and 48-51 each depend from claim 37. Claim 37 encompasses a genus of isolated nucleic acid molecules comprising a nucleotide sequence "the nucleotide sequence as set forth SEQ ID NO: 3". This phrase is indefinite as noted in the section, "Claim Rejections, 35 USC § 112, 2nd paragraph" but has been interpreted broadly to encompass any shorter nucleotide sequence found within the longer sequence of SEQ ID NO: 3. Claims 43 and 44 limit the nucleic acid to those encoding, respectively, a polypeptide consisting essentially of amino acids 28-346 (claim 43) or 28-426 (claim 44) of SEQ ID NO: 4. It is noted that the specification discusses nucleic acids encoding amino acids 27-344 of the murine receptor, which correspond to amino acids 28-346 of the human receptor (according to Figure 7). Similarly, one of skill in the

art would recognize that the mature human receptor consists of amino acids 28-426 of the human receptor. However, there is no conception in the specification of isolated nucleic acids consisting essentially of the recited regions (27-344 or 28-346), nor does the concept of each specific genus flow naturally from the disclosure of the specification. The specification does not use the term "consisting essentially of", and the term encompasses an unlimited number of changes to the sequence of the encompassed nucleic acids. Therefore, the specification as originally filed lacks support for claims 43 and 44.

Claims 48-51 depend from claim 37 and limit the nucleic acid to a sequence consisting essentially of nucleotides 142-1098 (claim 48); 142-1338 (claim 49); 142-414 (claim 50); or 415-1086 (claim 51). The specification does not teach nucleic acid sequences consisting essentially of these specific fragments of SEQ ID NO: 4. Therefore, the specification as originally filed lacks support for claims 48-51.

Applicants' arguments (5/10/06; pg 17) as they pertain to the rejection have been fully considered but are not deemed to be persuasive for the following reasons.

In the response dated 5/10/06, Applicants submit that they have amended the claims 37 and 38 in order to expedite prosecution. Applicants further submit that the recited nucleotide sequences in claims 48-51 can easily be determined by one skilled in the art in view of the disclosure of the specification and Figure 7, as amended.

Applicants' arguments have been fully considered but are not found persuasive. The claims as amended still encompass new matter, as described above. Claims 38-44 each encompass polynucleotides comprising specific fragments of the extracellular domain of SEQ ID NO: 4, and claims 43, yet the specification only teaches polynucleotides encoding a fragment comprising the entire extracellular domain of SEQ ID NO: 4. Claims 48-51 encompass polynucleotides comprising specific fragments of SEQ ID NO: 3; however the specification does not describe these particular fragments of SEQ ID NO: 3.

Applicants' argument regarding the ability of one of skill in the art to determine the specific regions in view of the teachings of the specification and Figure 7 is not persuasive. The issue is not whether the specification enables one of skill in the art to

make and use each genus of polynucleotides; rather the issue is whether or not the specification as originally filed conceived of each specific claimed genus of polynucleotides comprising fragments of the extracellular domain.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The instant specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116). Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 112, 2nd paragraph

Claims 1, 2, 7, 9, 10, 25, 28-30, 36, 37, 43, 44, 46-52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because the wording of the claim renders the metes and bounds of the claim indefinite. This claim could be interpreted in two different ways. First, it could be interpreted to limit the "isolated nucleic acid molecule" to comprising SEQ ID NO: 3 (including derivatives comprising SEQ ID NO: 3). However, it could also be interpreted to read that the "isolated nucleic acid molecule" comprises "SEQ ID NO: 3 encoding a haemopoietin receptor comprising an amino acid sequence set forth in SEQ ID NO: 4" or "a derivative of said receptor", thus encompassing fragments and other variants of SEQ ID NO: 3. If the first interpretation is intended, Applicants could (for example) amend the claim to clearly indicate that any claimed derivatives must also comprise SEQ ID NO: 3. Note that any amendments to the claims must have support in the specification. For purposes of prosecution, claim 1 is interpreted broadly to encompass nucleic acids encoding derivatives of the receptor of SEQ ID NO: 4.

Claim 2 is indefinite for the same reason as claim 1; it is unclear whether the isolated nucleic acid is limited to those comprising SEQ ID NO: 3 or whether it can comprise variants of SEQ ID NO: 3 that encode derivatives of the receptor.

Claim 7 is indefinite because it is unclear whether the final part of the claim (reciting, "...a nucleic acid molecule which hybridizes...") is limited by the first part of the claim reciting that the molecule encodes an IL-13 receptor. If Applicants intend the final part to be limited in such a manner, the claim could be amended such that parallel grammatical construction is used, e.g., "...said nucleic acid molecule having a nucleotide sequence as set forth in SEQ ID NO: 3 or having a nucleic acid sequence which hybridizes to..." (emphasis added by the Examiner).

Claim 37 is indefinite because the metes and bounds are unclear. It is not clear what is encompassed by "the nucleotide sequence as set forth SEQ ID NO: 3". A phrase such as "the nucleotide sequence of SEQ ID NO: 3" is clear and limited to the entirety of SEQ ID NO: 3. A phrase such as "a nucleotide sequence as set forth in SEQ ID NO: 3" is clear and broadly encompasses any shorter sequence (as small as two nucleotides) found within the longer sequence of SEQ ID NO: 3. In the instant case, the wording of the claim is such that it cannot be determined what the claim encompasses. For purposes of prosecution the claim will be interpreted broadly to encompass any shorter sequence (as small as two nucleotides) found within the longer sequence of SEQ ID NO: 3.

Claims 43, 44 and 48-51 are indefinite for the following reason. Each claim depends from claim 37 which recites, "An isolated nucleic acid molecule comprising the nucleotide sequence as set forth SEQ ID NO: 3". The use of the phrase "comprising the nucleotide sequence as set forth SEQ ID NO: 3" indicates that the nucleic acid of claim 37 must include the entirety of the SEQ ID NO: 3 (including each nucleotide from residue 1 to 1383). SEQ ID NO: 3 encodes a polypeptide of 426 amino acids. Therefore, the nucleic acid of claim 37 must encode a polypeptide comprising the entirety of this 426 amino acid protein. However, claims 43, 44 and 48-51 are each drawn to "The isolated nucleic acid molecule of claim 37, encoding a polypeptide consisting essentially" of specific amino acids residues of SEQ ID NO: 4 (i.e., 28-346 of

SEQ ID NO: 4). It is unclear how the independent claim can be limited to a nucleic acid encoding the entirety of a protein while the dependent claims are limited to encoding a polypeptide that consists of only a portion of the protein.

Claim 52 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection was set forth at pg 16-17 of the 11/7/05 Office Action. Specifically, claim 52 is indefinite because it recites "the isolated nucleic acid molecule of claim 38 comprising the amino acid sequence set forth in SEQ ID NO: 4". It is unclear how a nucleic acid can comprise an amino acid sequence. In this regard, this would be rendered definite if amended, for example, to recite "...nucleic acid molecule of claim 38 encoding the amino acid sequence..." In the 5/10/06 response, Applicants state they have "amended Claim 52 in accordance with the Examiner's suggestion. Accordingly, the rejection is overcome and withdrawal thereof is respectfully requested." However, the 5/10/06 "Listing of Claims" indicates that claim 52 is "Previously Presented" and there are no claim amendments made to the text of claim 52. Therefore, the rejection of the claim is maintained for the reasons set forth previously and reiterated herein.

The remaining claims are rejected for depending from an indefinite claim.

Claim Rejections - 35 USC § 102

Claims 45 and 46 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Lawman et al, U.S. Patent No. 5256560, published 10/26/1993.

Claim 45 encompasses any isolated host cell that expresses the haemopoietin receptor encoded by SEQ ID NO: 3. This claim encompasses isolated cells that recombinantly or naturally express this polypeptide. Claim 46 depends from claim 45 and limits the host cell to an animal cell.

The instant specification teaches that the polynucleotide of SEQ ID NO: 3 was isolated from a human bone marrow cDNA library (pg 39, line 17 to pg 40, line 7).

Therefore, isolated human bone marrow cells would inherently express a polypeptide encoded by SEQ ID NO: 3. Lawman teaches preparation of a cDNA library from bone marrow cells. Such a preparation would require isolation of the bone marrow cells. Therefore, the bone marrow cells taught by Lawman anticipate instant claim 45. Further, bone marrow cells are animal cells and anticipate instant claim 46.

It is noted that if Applicants wish to claim only recombinant cells expressing the receptor encoded by SEQ ID NO: 3, the claims could be amended to indicate that the claimed cells express a recombinant receptor (e.g., "An isolated host cell which recombinantly expresses the haemopoietin receptor encoded by SEQ ID NO: 3".), as taught by the specification (pg 29).

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary C. Howard whose telephone number is 571-272-2877. The examiner can normally be reached on M-F 9:30 AM - 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

zch

GARY B. NICKOL, PH.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600